be maintained upright to mimimize jostling and damage.

3.4 Routing

The Laboratory Supervisor assigns all work. Analysts are either assigned specific batches or take the sample with the next ID number. All samples are to be analyzed in sequential order unless assigned otherwise by the Supervisor. The Laboratory Supervisor assigns a specific sample or batch to an Analyst by notifying both the Sample Receiving Clerk and the Analyst. In either case, when accepting a sample, the Analyst records his name in the log book and the date and time he removes the sample from the "Incoming Sample" storage area.

3.5 Analysis and Data Gathering

All analyses must be carried out in accordance with the SOP(s) indicated in the log book. All SOPs used in this Laboratory will be found in the Appendices of this Manual.

Each SOP has a specific preprinted Data Recording Worksheet. Analysts are to obtain the appropriate worksheet from the Sample Receiving Clerk before begining an analysis. All data must be recorded on the sheet.

3.6 Data Reporting

Once an analysis of a sample is completed, the Analyst records the date and time in the log book and makes a photocopy of the Data Recording Worksheet. He gives the original to the Sample Recording Clerk and the copy to the Laboratory Supervisor.

The Laboratory Supervisor reviews the copy and notifies the Sample Recording Clerk of approval or rejection. The Laboratory Supervisor maintains the copy in his own file. If approved, the Sample Recording Clerk assigns a typist to complete a Final Client Report using the data recorded on the Data Recording Worksheet. Each SOP has its own specific Client Report. Typists are to use a sample report as a model to determine proper procedures for completing the Client Report.

The Sample Recording Clerk also completes the Chain of Custody documents, recording who performed the analysis, and date and time analysis was initiated and completed. The completed Client Report and

Chain of Custody are sent to the client and copies of those documents as well as the orginal Data Recording Worksheet are filed in the permanent Laboratory Master File.

If the Data Recording Worksheet is judged unacceptable, the Laboratory Supervisor can either require the Analyst to repeat those sections of the SOP judged questionable or assign another technician to them. In either case, a copy of the Data Recording Worksheet goes to the Laboratory Supervisor and the orginal to the Sample Recording Sheet. If results are acceptable, the preceding steps are then followed, including recording the time and date in the log book. All analysts who participated in the analysis of a sample must be recorded on all documents.

3.9 Disposal of Sample

Once the analysis is complete and the Data Recording Worksheet approved, the analyst disposes of the sample in the appropriate Disposal Box indicated in the SOP and records sample batch and ID numbers, and date and time in the storage log book. All Disposal Boxes are to be stored in a safe manner for the period of time indicated for that category of waste, in accordance with regulatory requirements. When a Disposal Box is full, the date of the most recent sample enclosed is marked on it. A new Disposal Box replaces the old one which is then to be stored until time of disposal when it is disposed in accordance with regulatory requirements.

4. EQUIPMENT AND CALIBRATION

4.0 Usage

A usage logbook is to be maintained for each instrument that requires calibration. At each use of an instrument the following information is to be recorded in it:

- Date and time of usage
- Initials of analyst
- Sample ID and batch # of sample in which analysis was performed on

4.1 Calibration

Calibrations of instruments are necessary to maintain our high standards of results and to provide our clients with legally defensible data on which to base decisions. Therefore all laboratory personnel are required to comply with calibration procedures of this Laboratory.

Instruments are to be calibrated on a regular basis in accordance with frequency of use. The calibration schedule of each instrument will be established by the QA Manager. A Calibration SOP for each instrument can be found in the Appendices of this Manual.

All Calibration SOPs must be in accordance with regulatory agency requirments and will include complete descriptions of calibration, required calibration curves and calibration schedule.

A Calibration Logbook will be maintained for each instrument. A calibration curve will be maintained for each instrument whose SOP calls for it. All logbooks and curves must include the following:

- Calibration schedule
- Date and time of each calibration
- Initials of analyst who performs calibration
- Number of times instrument used since last calibration
- Pertinent comments

All analysts are responsible for compliance with calibration requirements and must check the usage logbook for the instrument about to be used before carrying out an analysis. If the logbook indicates a calibration is due, that analyst must do it, even if he must interrupt an anlysis of a batch of samples.

4.2 Maintenance

Maintenance schedules for equipment will be established by the Laboratory Director. The Laboratory Director shall also determine whether each instrument is maintained and repaired in-house or by an outside agency. Servicing will also be performed when indicated by dramatic changes in calibration.

A maintenance logbook will be maintained for all equipment which will contain a maintenance checklist, schedule and log sheet for each instrument. The schedule will be in the form of a table with maintance elements listed by row and frequency by column:

Frequency: / Maintenance Elements	1 mo.	2 mo.	3 mo.	4 mo.

Each istrument maintenance log sheet shall contain the following information:

- Date and time
- Initials of who performaed servicing (include if in-house or outside agency)
- Scheduled or unscheduled check
- Maintenance element examined and if any repairs/replacement of component; were made
- Pertinent comments
- Due date for next servicing

The Laboratory Supervisor is responsible for ensuring these routine maintenance schedules are enforced.

4.3 Manuals

The QA Director is responsible for maintaining and reviewing all instrument manuals pertaining to calibration and maintenance. Any noteworthy items are to be included in the monthly QA report.

The QA Director additionaly distributes the manufacturer's manual on each instrument to the head of each department in which the particular instrument is located. It is the policy of this Laboratory to be informed of and current with all

new releases of information on all utilized equipment. Therefore the QA Director is also responsible for receiving and distributing all updates on manufacturer's manuals to the appropriate department heads.

5 QUALITY OF MATERIALS

The high quality of materials used in this Laboratory shall be assured through specific purchasing and verification procedures and/or proper preparation techniques.

5.1 Reagents

The reagents used in this Laboratory are to be classified into three levels of use priority:

1. Industrial Grade
2. Analytical Grade
3. Special High Priority Grade

Selection of the appropriate grade of reagant(s) is designated in the reagant section of each analysis SOP and in addition may be specified by the Laboratory Supervisor in unusual circumstances.

Reagents shall be purchased in accordance with the analysis needs of this Laboratory as determined by the Laboratory Director. Reagent preparation is described in Section 6 -- Laboratory Practices of this Manual.

Verification will consist of confirming that the priority grade is recorded on the reagent label unless analysis difficulties indicate a possible problem or regulatory agency requirements specify otherwise. In the latter case, the appropriate analytical SOP will indicate the proper verification procedure.

5.2 Apparatus

All apparatus shall be maintained in good condition and in working order. Any items found to be defective will be taken out of use and repaired or, if necessary, replaced.

Analysts will use apparatus for the intended purpose and not needlessly expose items to corrosive materials and/or inappropriate conditions such as allowing acid to boil over onto hot plates. Apparatus and equipment shall not be used for food preparation.

Verification will consist of one of the following procedures:

- o Standard manufacturers' labels
- o Letter from the manufacturer certifying that the purchased item is of the selected type and class and is manufactured to specifications
- o In accordance with regulatory agency requirements
- o In accordance with specific procedures developed by the QA Director

The QA Director will determine which of these procedures is to be followed for each piece of apparatus.

5.3 Consumable Supplies

Consumable supplies are to be purchased on the basis of analysis needs as determined by the Laboratory Director. Analysts are to use the appropriate items as specified in analytic SOPs. SOPs will indicate the specific grades and classes of consumable supply items to be used. Analysts are not to re-use expendable materials intended for single-use purposes such as filter paper.

Verification procedures will be one of the following:

- o Each shipment of consumable supplies will be tested at the rate of 1% in accordance with procedures established by the QA Director at the time of arrival
- o Standard manufacturers' labels
- o Letter from the manufacturer certifying that the purchased item is of the selected type and class and is manufactured to specifications
- o In accordance with regulatory agency requirements

The QA Director will select the verification procedure for each type of consumable supplies.

6 LABORATORY PRACTICES

This Section describes reagent control, contamination management and use of controlled procedures for this Laboratory. Proper observance of these procedures is necessary to guarantee the safety of Laboratory staff members.

6.1 Reagent Control

Reagents will be prepared either according to the analytic SOPs specifying their usage (if a reagent is not commonly used in this Laboratory) or in a separate compendium of reagent SOPs (if a common reagent). All such documents are located in the Appendices of this Manual.

All reagents will be stored in either their orginal containers or, if prepared in this Laboratory, in specified containers used for this purpose. All reagent container labels will bear the following information:

- Active component
- Matrix description
- Concentration
- Date prepared
- Expiration date
- Technician who prepared it (if in-house)
- Manufacturer/supplier (if prepared outside)

All reagent containers are to be stored in a non-combustible, properly ventilated room in a flammable materials cabinet. Handling of volatile reagents is performed under a ventilated hood with rubber gloves for the safety of Laboratory personnel.

Small quantities of commonly used reagents are kept at work stations to facilitate their use during the work day. Those specific materials will be determined by the Laboratory Supervisor.

6.2 Contamination Management

Contamination both of samples and of the environment (including reagents used in analysis) must be avoided to provide the highest quality, legally defensible data to our clients. In order to achieve this goal, Laboratory staff must adhere to various preventative measures and use the regular testing procedures for contamination detection as established by the QA Director.

6.2.1 Contamination Control

Contamination control is focused both on sources and targets of contamination. Sources would include:

- Samples
- Laboratory debris

Targets would include:

- Samples
- Equipment, such as tools
- Supplies, such as slides and mounting media
- Work areas

Contamination control programatically consists of 2 parts:

- Avoidance
- Verification

To avoid contamination of the previously listed targets, the following procedures must be followed:

- Cleanliness (housekeeping)
- Controlling work areas
- Isolating pathways

To achieve cleanliness, Laboratory personnel will comply with the following steps:

1. Clean all tools before and after preparing each sample.

2. Clean and wrap tool sets at the end of the work day.

3. Dispose of wipers after use. Do not let them pile up during the work day.

4. Wipe all work surfaces before and after sample preparation. Surfaces include bench tops, slide trays, stereo microscope stage, and slide preparation surface.

Work areas should be controlled as follows:

1. Bulk samples are opened and examined using the stereo microscope only in the hood.

2. Slides are prepared only in the hood.

2. Slide preparation or sample handling shall occur only in the assigned areas. Only prepared slides in a slide tray or other clean surface shall be kept in that area.

3. Small numbers of active samples are kept near the hood. The sample containers are kept closed at all times. Inactive samples are stored in a suitable, out-of-the-way, area.

Laboratory personnel will comply with the following procedures to isolate contamination pathways:

1. Target containers - for example, samples, mounting media, slides, cover glasses - are opened one at a time. Each is closed before another is opened. Two target containers are not to be opened simultaneously.

2. Prepared slides are stored in a protected manner. Covered slide trays are ideal.

3. Mounting media never touches a sample. Place media on a clean slide before the sample is placed there.

Analysts are to work only on clean surfaces.

6.2.2. Verification of Control

In addition to the previously dilineated steps, contamination control must be verified. An example of this procedure for slides is as follows:

1. At the start and end of each day a blank slide, consisting of mounting media and a cover glass, is prepared and examined.

2. If the start-slide shows contamination, the area and tools are cleaned, and another slide is prepared. If the second slide shows contamination, another bottle of mounting media is checked. If the second bottle is clean, the first bottle is considered contaminated. If the second bottle also shows contamination, a complete investigation is conducted to determine the contamination source.

4. If the end-slide shows contamination, the same steps are taken. In addition, all samples done that day by that analyst that contain less than a predetermined percentage (generally 10%) of the analyte of interest are checked.

5. At least once a week prepare a slide from a homogenous, non-fibrous, reagent grade material that is permanently stored in the microscope hood. If contamination is noted, take the steps described above.

The weekly blanks are recorded in a separate log book. Daily blanks are recorded only if contamination is found. Neither of these blanks are to be used for statistical quality control.

6.3 Controlled Procedures

Only controlled procedures, i.e., controlled SOPs as described in Section 7 -- Documentation Preparation and Control, shall be used in analyses in this Laboratory. No unauthorized SOPs are to be used.

7 DOCUMENTATION PREPARATION AND CONTROL

In order to prepare and distribute documents in an organized fashion, ~~the~~, the following procedures for initiation, preparation, review, approval and issuance of controlled copies will be followed. This program is a coordinated effort involving both technical review and custodial control. Analysts are to use only controlled, i.e., approved, documents for all calibrations, analyses and other activities performed in this Laboratory. Documents include:

- o Analytic SOPs
- o Reagent preparation SOPs
- o Calibration SOPs
- o Contamination management SOPs
- o Quality Assurance Manual

7.1 Initiation and Preparation

Initiation of a new document or a request for revision of an existing document can arise from a variety of sources within this Laboratory. Such sources include any employee involved in laboratory operation such as secretaries, analysts, Laboratory Director, QA Director, Laboratory Supervisor, Analysts and the Sample Receiving Clerk. Assignment of preparation or revision of a document will vary depending on its purpose. However, the person most familiar with the material covered in the document generally will be the person so assigned and that decision will be made by the Laboratory Director.

7.2 Review and Approval

Once the individual assigned to the preparation and or revision task has completed a first draft of the new document, it will be submitted for review according to the normal chain of command in this Laboratory. In other words every staff member above that individual will see the document and make any necessary comments. No matter who prepares a document the Laboratory Director and QA Director must be included. A typical document affecting a task performed by an analyst would be prepared by the analyst and submitted for approval to the Laboratory Supervisor of that particular department, QA Director and Laboratory Director.

Once the document has gone through the chain of command, the preparer institutes all approved changes and submits it again for what is (normally) the last review. The Laboratory Director gives final approval to all documents and procedures.

7.3 Distribution of Controlled Copies

In this Laboratory, only controlled copies of procedural documents will be issued in order to ensure the following:

- that all laboratory activities are carried out in a uniform fashion
- that distribution of SOPs and other documents is organized
- to facilitate updating these documents

The QA Director is responsible for distribution and control of approved documents.

Each copy of a document is assigned a specific number. The original document along with a Document Distribution Form for every copy will be maintained in the Master Laboratory file. The Distribution form will list the document title; copy number; version; name, title, and signature of the individual receiving that copy; and the date the copy is received. Every time a revised document is issued, the outdated version will be exchanged to assure implementation of revisions. The new information will be recorded on the appropriate Distribution Form.

8 REPORTING RESULTS

8.1 Client Report Requirements

As described in Section 3 -- Sample Tracking of this Manual, all data performed in this Laboratory shall be recorded on preprinted Data Recording Worksheets. Each SOP has its own specefic Worksheet.

Final Client Reports are prepared by typists from Data Recording Worksheets that have been approved by the Laboratory Supervisor. Each final report will have the following information:

- Laboratory identification and address
- Name and address of client
- Department(s) performing analyses and date
- Sample IDs and descriptions
- Sampling procedure
- Identification and description of test procedures performed
- Any deviations or additions to test specifications
- Statement of measurement uncertainty
- Statement of authenticity of results signed by Laboratory Director
- Statement that report cannot be reproduced except in full with the approval of this Laboratory
- Statement that this report relates only to the items tested

8.2 Approval

All Final Client Reports are to be reviewed and approved by the Laboratory Director prior to being sent to the client. They are also subject to approval by the QA Director. Quality Control statistics shall be reviewed on a regular basis as determined by the QA Director in accordance with regulatory agency requirements and dilineated in the appropriate SOPs. As long as those statistics are deemed acceptable, Client Reports will continue to be processed.

8.3 Records Retention

The following records shall be maintained for three years in the Laboratory Master Files:

- Copy of Chain of Custody Documents
- Client Report
- Original Data Recording Worksheets
- Location of all other records relating to the prepartion of the Client Report

Client Reports are to be filed by client name and by Job number.

Each department within this Laboratory shall retain the following records in their permanent files for three years:

- Copy of Data Recording Worksheets
- Calibration, usage, and verification data
- Contamination monitoring data
- Equipment and maintenance
- Performance monitoring

All records must be maintained in sufficient condition so as to meet regulatory agency requirments and to withstand regular inspections by those same agencies.

9 PROCEDURES FOR DEALING WITH CLIENT COMPLAINTS

If a client makes a complaint about a test result, the sample in question will be reanalyzed by a second Analyst. If the second result agrees with the original (is within the original's uncertainty range), the Laboratory Director shall send a letter stating that a quality control check has confirmed the original analysis.

If the second result does not agree with the original, a third Analyst shall perform a test to determine the correct analysis. If this third result rejects the original analysis, the Laboratory Director shall send a letter to the client stating that a quality control check has found the orginal analysis in error. The letter should either accompany an amended Final Client Report or state that such a report will be sent shortly. In either case, the ammended report will contain the corrected result that was confirmed by two Analysts.

10 TECHNICAL QUALIFICATIONS

Analysts are required to meet certain training and performance criteria as mandated by federal and state regulations and by this Laboratory's hierarchy before being permitted to analyze samples and perform procedures on a routine basis. The following sections describe the formal and informal training programs as well as the opportunities provided for on-the-job review. Procedures for new technicians to obtain authorization to perform analyses as well as review and approval of those analyses and future quality characterization are also described.

10.1 Training

Training for all analyses performed in this Laboratory according to the SOPs found in the appendices of this Manual shall consist of formal and informal training as well as opportunities for on-the-job review.

10.1.1 Formal Training

Formal training will consist of a 2-year Associates Degree or higher in Chemistry or Chemical Technology at an accredited institution. Alternatively, formal training requirements may be met by "equivalent professional experience" as defined by federal law.

In addition, Analysts will be required to complete training seminars and mini-courses on use of instruments used in this Laboratory offered by manufacturers of those instruments.

10.1.2 Informal Training

Informal training for a new Analyst with minimal experience will take place on the job and consist of the following steps:

1. The trainee will be asked to study the appropriate SOPs for sample and reagent preparation, analysis and instrument calibration.

2. The trainee will observe an experienced Analyst perform the reagent preparation, sample preparation and analysis, and instrument use and calibration procedures.

3. Ample opportunity will be provided for

the trainee to continue to practice analyses by using samples previously analyzed by ~~by~~ an experienced technician.

4. When formal and informal training has been completed, including sufficient opportunity for the trainee to practice all required procedures, his or her performance will be evaluated prior to being given authorization to perform analyses as described in Section 10.2 of this Manual.

For more experienced new Analysts, the Laboratory Supervisor will determine which of the previous steps may be bypassed with the exception of items 1 and 4.

10.1.3 On-The-Job-Review

Formal reviews of each Analyst's job performance will occur two times each year counting from the initial date of employment.

In addition, all aspects of each Analyst's work will be subject to ongoing on-the-job review by his/her Laboratory Supervisor who will provide the appropriate feedback as needed.

Examination of all Quality Control sample analyses performed by Analysts will provide information for on-the-job review. All analysts' performances will be monitored as described in Section 11 of this Manual. If the Quality Control statistics indicate out-of-control points on the control chart, or if an Analyst has an increase in number of rejections or deviations from expected quality control results over a previous period of time, one of the main corrective actions to be taken will be to provide an opportunity for on-the-job review.

Analysts are always encouraged to consult with each other on any analysis difficulties. This type of confirming analysis is a less structured but equally significant aspect of review procedures and quality control. To perform a confirming analysis, one Analyst notes the results of another and checks to see if he agrees with the results. The first step taken as a corrective action if these results do not

agree, or for inconsistencies found with other Quality Control samples, is for the two Analysts to examine the sample together, discuss it, and come to an agreement on the results. Such consultations provide another input for on-the-job review.

10.2 Authorization to Perform Analysis

The procedure to obtain authorization to perform analysis consists of an evaluation process, review and approval and ongoing quality characterization.

10.2.1 Examination Process

After the Analyst Training Program has been completed, each new Analyst will be evaluated before being given authorization to perform analyses.

A Quality Card on each Analyst will be maintained and stored in the personnel section of the Laboratory Master files. The card will list the name of the SOP for every analysis performed in this Laboratory. As the new Analyst attains proficiency in performance of a particular analysis, as determined by the Laboratory Supervisor, that Laboratory Supervisor will note, date and sign the Quality Card in the appropriate spot. In addition, records of the Analyst's test performance (whether it results in authorization or not) will be maintained in the files.

The examination to determine proficiency for an SOP will have two sections: a re-analysis of samples already analyzed by an experienced Analyst and analysis of quality control samples. The Supervisor will use the results of both areas to determine competence.

The new Analyst's result must agree with that of the experienced Analyst within the realm of margin of error. Performance must fall within the action limits on the control chart for overall lab performance. Quality control results must be on par with the rest of Laboratory personnel.

If the new Analyst fails to obtain authorization at this time, he will be asked to consult with an experienced Analyst on test descrepancies. Any further training

measures deemed necessary will be implemented, and the Analyst will be asked to continue to practice by reanalyzing other technicians' samples. When the new Analyst is ready for a retest, he will repeat the process.

10.2.2 Review and Approval

When the Laboratory Supervisor determines that the new Analyst meets all criteria as previously described, the results of the tests will be submitted to the Laboratory Director for review and approval prior to the Analyst receiving authorization to perform the analysis.

10.2.3 Quality Characterization

Once a new Analyst receives authorization to perform analyses, the quality of his performance will be monitored as described in Section 11 of this Manual. Such performance will be part of both informal on-the-job review and formal semi-annual review.

The above procedures also appply to experienced personnel who wish to attain proficiency in new areas for the purpose of career advancement.

11.0 PERFORMANCE MONITORING

The overall Quality Control program as established and managed by the QA Director ensures that this Laboratory is fulfilling our commitment to our clients, that our data is legally defensible and that all personnnel perform their responsibilities properly.

The Quality Control program includes intra-lab sample testing, participation in inter-lab programs and statistical analysis.

11.1 Intra-lab Sample Testing

Each analysis performed in this Laboratory has its own Quality Control requirements which have been determined by the QA Director and are delineated in that SOP. These requirements are in full compliance with the NYS DOH ELAP program and are detailed in the ELAP manual. These requirements include at least one if not all of the following:

- o Replicates

  A portion of a sample is prepared and reanalyzed by the original analyst. The Analyst will then submit his result to his Supervisor who reviews it and in turn submits it to the QA Director for statistical evaluation.

- o Duplicates

  A portion of a sample is prepared and reanalyzed by a second Analyst. The Analyst will then submit his result to his Supervisor who reviews it and in turn submits it to to the QA Director for statistical evaluation.

- o Reference

  Known standards and blanks are relabeled, prepared and analyzed as if they were samples.

- o. Spike

  A known quantity of the analyte of interest is added to a sample which is then relabeled, prepared and analyzed.

- o Surrogate

  A known quantity of a substance other than the analyte of interest is added to a sample which is then relabeled, prepared and analyzed. This procedure is usually reserved for SOPs involving chromotography.

The QA Director will determine how QC testing is implemented, either on a frequency basis, e.g., after the analyses of every ten samples, or on a percent of workload basis where QC testing occurs on a regular basis with, for example, 10% of the previous time period's workload tested. This is also delineated in the SOPs and is dependent on the analyte in question. The QA Director in addition will inspect the results of all QC testing on a regular basis and provide the necessary support and directives to the Laboratory Director to ensure the QC program is properly executed.

In all cases, the NYS DOH ELAP requirements are taken as a minimum. Other QA/QC protocols may be required, depending on the sample type, e.g., food samples require FDA protocols.

Additionally, the laboratory will perform custom QC for a client upon request. Such custom QC protocols will be worked out with the client, and the client will be furnished with all QC data, including control charts, for those samples. The cost of such work will be decided by the Laboratory Director, and must have his approval. Custom QC protocols, at a minimum, must meet NYS DOH ELAP requirements.

The Laboratory Supervisor (Department Head) of each department is responsible for implementing the day-to-day QC testing and ensuring the correct type of testing at the appropriate frequencies occur. The Labortory Supervisor is also responsible for ensuring complete records of QC testing are maintained. Data collection is described in Section 11.4.1.

11.2 Inter-lab Program

This laboratory will participate in both proficiency and round robin testing programs with outside organizations.

11.2.1 Proficiency Testing

This Laboratory participates in the mandatory proficiency testing administered by the NYS DOH ELAP program and in the voluntary testing administered by the American Industrial Hygiene Association (AIHA) and the Environmental Protection Agency (EPA). The QA Director determines which of the latter two organizations' programs each department takes part in. This decision is based on the particular analysis areas of each group.

In all programs each organization sends four samples and one blank at regularly scheduled intervals which will be determined by the QA Director. These samples are analyzed by at least five Analysts and results are averaged to obtain the final result reported to the testing agencies. The organizations then evaluate the results by determining if they are within the acceptable three standard deviations range based on the results of all participating laboratories. The number of standard deviations each result is from the mean is also reported.

11.2.2 Round Robin Testing

This Laboratory is currently part of a round robin testing program which includes two other area labs. All samples for each type of analysis performed in this Laboratory are exchanged on a semi-annual basis. Results are compared.

The QA Director recommends the particular outside labs, maintains contact with the equivalent officials at those organizations and coordinates the process for this Laboratory.

11.3 Data Validation

At regular intervals which will be determined by the QA Director, all QC data will be scanned for questionable values. Criteria for judging a result quesitonable will include deviation from prior data from the same sample, from another sample within the same job batch, or from a sample collected at the same site within one month of the time of collection. Any questionable results will be rechecked with other Quality Control samples.

11.4 Statistical Analysis

Copies of all data produced in intra-lab and round robin testing will be handed in by the Laboratory Supervisors to the QA Director. The QA Director then carries out the appropriate statistical analysis. Data collection and statistical analysis are described in the following.

11.4.1 Data Collection

Quality Control data are recorded in bound notebooks with separate sections for replicate, duplicate, reference, spike and surrogate analysis. Information included in these sections is to include:

- Date of original analysis
- Sample ID
- Relabeled ID
- Original and where appropriate duplicating Analysts
- Original result and second result

Each department will maintain its own notebooks for each SOP and hand them in to the QA Director on a regular basis as dilineated in the SOP.

11.4.2 Data Evaluation

The QA Director will plot the data to create control charts, graphs and spreadsheets as called for by regulatory agencies and dilineated in each SOP. Control charts will contain warnings and action limits for reference samples.

In addition, the QA Director will prepare a monthly report highlighting the following:

- Summary of all QC activities
- Results of investigations of any QC out-lier results
- Overall laboratory performance
- Results of any internal or external audits

12 PERFORMANCE CRITERIA

Both standards of performance and corrective action to be taken when those standards are not met are discussed in this section

12.1 Performance Critera and Standards

Performance criteria will be determined two ways.

1. Results from intra-lab and round robin testing will be plotted to see if they fall within warning and action limits.

2. The administering agencies for proficiency testing will determine performance criteria.

Either or both methods may be used and this is dilineated in each SOP. Performance criteria results will be maintained for both individual Analysts and for the entire Laboratory where applicable.

12.2 Corrective Action

Corrective action will be taken when results fall outside performance levels, i.e., outside warning and action limits. The QA Director is responsible for flagging such occurances and reporting them to the Laboratory Supervisor who then takes the appropriate action to determine the ~~the~~ reason for the unacceptable result.

If an Analyst is found to be at fault, the occurance is documented and placed in the personnel file of that Analyst. If the Analyst is found to be performing below par, individual informal training will be provided. A record of the training will be placed in that Analyst's personnel file.

In round robin testing, this Laboratory's results must be within two standard deviations of the mean of the other two participating laboratories' results. If they are not, and a review of other Quality Control Statistics from this Laboratory indicates the problem is not internal, a joint meeting with the other two labs will be held to discuss the disparity. As a final, drastic step, ~~t~~termination of the association with the outside lab deemed at fault and participation with another lab will be considered.